

Message

---

**From:** Elizabeth Erwin [Erwin.ElizabethLNDU@usepa.onmicrosoft.com]  
**Sent:** 7/12/2011 2:54:24 PM  
**To:** Kadry, Abdel-Razak [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acb325507bf7451b9735813cfde5e417-Kadry, Abdel-Razak]; Sasso, Alan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cb867519abc4dcea88149d12ef3e8e9-Sasso, Alan]; Davis, Allen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8ecee8c29c54092b969e9547ea72596-Davis, Allen]; Boone, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=304ccd01957044a1bd50a366d1cd76d4-Boone, Amanda]; Persad, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd13fdf1bd814755baac109c2ab990a0-Persad, Amanda]; AmandaM Evans [Evans.AmandaMLNDU@usepa.onmicrosoft.com]; Hotchkiss, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10f01ccc8611401bb34d16b71a87d3d5-Hotchkiss, Andrew]; Kraft, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a94a4f199b247778abb02285a51b927-Kraft, Andrew]; Anne Grambsch [Grambsch.AnneLNDU@usepa.onmicrosoft.com]; Gatchett, Annette [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f12d699a71f84e21bddbb876dae7f96c-Gatchett, Annette]; Luke, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b98bf69c14b142d3ac8e0e9132ee36ed-Luke, April]; CN=Audrey Hoffer/OU=DC/O=USEPA/C=US@EPA; Buckley, Barbara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bb6dedc12624295b9e8e5f835a1f166-Buckley, Barbara]; Glenn, Barbara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a2dc9210d2d4d02a623b33f87f49436-Glenn, Barbara]; Barbara Wright [Wright.BarbaraLNDU@usepa.onmicrosoft.com]; Clark, Becki [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a906e07f1cd143b9a3c2ddab813b8140-Clark, Becki]; Hawkins, Belinda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=075561d171e845828ec67a945663a8e6-Hawkins, Belinda]; Zwyer, Bette [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79830e38edb14034b7e47e29ed213dab-Zwyer, Bette]; Bob Frederick [Frederick.BobLNDU@usepa.onmicrosoft.com]; Bob Sonawane [Sonawane.BobLNDU@usepa.onmicrosoft.com]; Brenda Carmichael [Carmichael.BrendaLNDU@usepa.onmicrosoft.com]; Gibbons, Catherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2ac775a35a0945718edc7e02f50e6c12-Gibbons, Catherine]; Charles Ris [Ris.CharlesLNDU@usepa.onmicrosoft.com]; CN=Chon Shoaf/OU=RTP/O=USEPA/C=US@EPA; Cubbison, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e1b702ba5f394a15a49c5efad199035a-Cubbison, Christopher]; Parsons, Christy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bf0dabe0c058478294128cb3f842573d-Powers, Christina]; Cai, Christine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e5901665d14498983704fd9eeda0dd8-Cai, Christine]; Christine Ross [Ross.ChristineLNDU@usepa.onmicrosoft.com]; Christopher Sheth [Sheth.ChristopherLNDU@usepa.onmicrosoft.com]; Petersen, Dan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05e14a620a164436adfae701533b4cd5-Petersen, Dan]; Moore, Danielle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=979ea3cb9c2f4da4ac701d93cb24c17d-Moore, Danielle]; Winner, Darrell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=860556f5cd0f4855839907bcc90b2c41-Winner, Darrell]; Bussard, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf26b876393e44f38bdd06db02dbbfe5-Bussard, David]; Segal, Deborah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bccd984267644f3fb89ea65f65e6f422-Segal, Deborah]; Debra Walsh [Walsh.DebraLNDU@usepa.onmicrosoft.com]; Hutchins, Debra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38b89ba9317a475ca671ae9fe840e00d-Jones, DebraL]; Shaw, Denice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=556182b3879649039b11d36e5e09d9aa-Shaw, Denice]; CN=Doug

Johns/OU=RTP/O=USEPA/C=US@EPA; Corona, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=18d86fb8269b4557b5d06622b3a941af-Corona, Elizabeth]; Elizabeth Erwin [Erwin.ElizabethLNDU@usepa.onmicrosoft.com]; Eva McLanahan [McLanahan.EvaLNDU@usepa.onmicrosoft.com]; Lehmann, Geniece [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=949a2f9c9f9f484581c3d00b118193e6-Lehmann, Geniece]; Perovich, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e3c19d7f4db41bfa2477aa27ad83945-Perovich, Gina]; Suter, Glenn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86ff3a58b76b40e4a75d9441bd584153-Suter, Glenn]; Harlal Choudhury [choudhury.harlalLNDU@usepa.onmicrosoft.com]; CN=Helen Knecht/OU=CI/O=USEPA/C=US@EPA; Hui-Min Yang [Yang.Hui-MinLNDU@usepa.onmicrosoft.com]; Ila Cote [Cote.IlaLNDU@usepa.onmicrosoft.com]; Avery, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0fc9e70467647709fa9377dfb987f10-Avery, James]; James Ball [Ball.JamesLNDU@usepa.onmicrosoft.com]; Strong, Jamie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea753aafefb74c268550fe6a2c187838-Benedict, Jamie]; Gamble, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f345a4a1e5e45fdbb51817c8d129f95-Gamble, Janet]; Frithsen, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3743bd6f3c345baaae407c1d6f78e92-FRITHSEN, JEFF]; Jennifer Jinot [Jinot.JenniferLNDU@usepa.onmicrosoft.com]; CN=JMichael Davis/OU=RTP/O=USEPA/C=US@EPA; Vandenberg, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcae2b98a04540fb8d099f9d4dead690-Vandenberg, John]; Kaiser, Jonathan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8d90ca09c2744f080d333034ee08fe7-Kaiser, Jonathan]; CN=Jordan Trecki/OU=DC/O=USEPA/C=US@EPA; Karen Hammerstrom [Hammerstrom.KarenLNDU@usepa.onmicrosoft.com]; Kate Guyton [Guyton.KateLNDU@usepa.onmicrosoft.com]; Deener, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9a2ff1c086249ea8f6414afde8a5e54-Deener, Kathleen]; Newhouse, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5f019c8179304045acd61bc05b571fb0-Newhouse, Kathleen]; Raffaele, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc48281bbab34bf5bf3ab1a63780d5ca-Kathleen Raffaele]; Kelly Serfling [Serfling.KellyLNDU@usepa.onmicrosoft.com]; Krista Christensen [Christensen.KristaLNDU@usepa.onmicrosoft.com]; Alexander, Laurie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b0c420c5c71464b922e50788a1c22de-Alexander, Laurie]; Kopylev, Leonid [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=abfe6798809e4c8c8a27452ec86726d8-Kopylev, Leonid]; Lisa Vinikoor-Imler [Vinikoor-Imler.LisaLNDU@usepa.onmicrosoft.com]; Lucy Curtis [Curtis.LucyLNDU@usepa.onmicrosoft.com]; Flowers, Lynn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a4411c874d041b9a8badfc32b91bd70-Flowers, Lynn]; CN=Madalene Stevens/OU=DC/O=USEPA/C=US@EPA; Field, Malcolm [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8d12938447d14c7babcf431d75d745f6-Field, Malcolm]; Pratt, Margaret [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8eda90b62a874c7ea9d857903ac1fd14-Pratt, Margaret]; Maria Spassova [Spassova.Maria@epa.gov]; Marian Rutigliano [Rutigliano.MarianLNDU@usepa.onmicrosoft.com]; Martin Gehlhaus [Gehlhaus.MartinLNDU@usepa.onmicrosoft.com]; Ross, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98359cd1f66f46ec91d327e99a3c6909-Ross, Mary]; Gwinn, Maureen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bdc5237a5c440a7b664518e23eb5647-Gwinn, Maureen]; Michael Slimak [Slimak.MichaelLNDU@usepa.onmicrosoft.com]; Troyer, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=847b0020dd0e457e85f994a1ad64b26d-Troyer, Michael]; Wright, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0087b3fe163145869deead8b626fbfa3-Wright, Michael]; Keshava, Nagalakshmi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d125c2980ab348ec828ba8f513b95049-Keshava, Nagalakshmi]; Birchfield, Norman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c910f2fd28414e819b6afe6dda525e9f-Birchfield, Norman]; CN=Patricia Gillespie/OU=RTP/O=USEPA/C=US@EPA; Murphy, Patricia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e02a7540f8042fda07eed1248addaf7-Murphy, Patricia]; Schlosser, Paul

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=121cf759d94e4f08afde0ceb646e711b-Schlosser, Paul]; White, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e179825823c44ebbb07a9704e1e5d16-White, Paul]; Peter Preuss [Preuss.PeterLNDU@usepa.onmicrosoft.com]; Sams, Reeder [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d5b479ccd894cea99ae55df20de6971-Sams, Reeder]; Jones, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eac77fe3b20c4667b8c534c90c15a830-Jones, Samantha]; Barone, Stan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4f8618acbb418da24c110f3123a2af-Barone, Stan]; Stella Spyropoulos [Spyropoulos.StellaLNDU@usepa.onmicrosoft.com]; Vulimiri, Suryanarayana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a4f972302434ec6a04b015b14845a9d-Vulimiri, Suryanarayana]; Makris, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7654051d8d1240a39dfa9463c9b0b7e5-Makris, Susan]; Rieth, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00aac63cc995489188b8a449aaa18f5e-Rieth, Susan]; CN=Suzanne Martos/OU=DC/O=USEPA/C=US@EPA; Berner, Ted [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1949c9653024d3cb4aa4c2bd69c4fde-Berner, Ted]; Teneille Walker [Walker.TeneilleLNDU@usepa.onmicrosoft.com]; Bateson, Thomas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29bfdde020bf4e93b431b9a72d9d230f-Bateson, Thomas]; Blessinger, Todd [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5240ca690c84f8fb20bac6fd7273fd5-Blessinger, Todd]; Long, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7526c52b77aa4516b9ac197536e5a6a0-Long, Tom]; Cogliano, Vincent [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51f2736376ac4d32bad2fe7cfef2886b-Cogliano, Vincent]; Weihsueh Chiu [Chiu.WeihsuehLNDU@usepa.onmicrosoft.com]

**Subject:** NEWS UPDATES: Industry Looks To Peer Panel To Reverse EPA's Methanol Study 'Discounts' (Risk Policy Report)

## Industry Looks To Peer Panel To Reverse EPA's Methanol Study 'Discounts'

Posted: July 11, 2011

Industry groups are looking to an upcoming peer review panel to reverse EPA's proposed decision to discount the results from a series of studies that the groups had hoped would soften the agency's proposed non-cancer risk assessment of methanol, and are reiterating their calls for EPA to withdraw the draft assessment.

EPA recently agreed to weigh the results from a series of studies by University of Toronto professor Peter Wells, as well as several others, and included them in a June 16 addendum to its draft Integrated Risk Information System (IRIS) methanol study. Industry groups were initially optimistic that EPA's inclusion of the study results could help soften the proposed risk values because the studies raise questions about the agency's extrapolation of risk data from mice to humans (*Risk Policy Report*, June 28).

But the agency in the addendum discounted some of the industry-backed study results, finding, in one case, that although the study lacked statistically significant data sets, it nevertheless presented data showing increased risk of developmental harms. EPA also declined to consider another study that industry hoped would help soften the agency's proposed risk values.

Now methanol industry groups are hoping that members of peer review panel, who are meeting July 22, in Durham, NC, will take into account the industry-funded research and reject the agency's attempts to discount the findings.

"The positive take away here is that [the addendum] puts the Toronto research in front of the peer review panel," says one industry source. "This is an opportunity for those peer reviewers to see this research and make their own judgment."

But even if the peer review panel does support the industry-backed studies, EPA has no obligation to follow its recommendations, which was at issue in a recent assessment of formaldehyde that has led to serious criticism of the IRIS program and the agency as a whole. "The EPA is under no real obligation to respond or incorporate any of the comments that come up during peer review," concedes the source. "But we remain hopeful that the agency, in its effort to advance the best available science, will take them into account."

Methanol is a chemical widely used in the production of alternative and renewable fuels, paints, plastics, solvents and textiles. EPA says it anticipates increased demand for methanol, especially in biodiesel production, although the agency says the need is "growing steadily in almost all end uses." EPA is proceeding with its noncancer assessment after almost a year of delay as agency officials grappled with how to handle data from a controversial Italian lab that was the basis of its cancer risk assessment for the substance. Industry protested the use of the Ramazzini Institute data, arguing that its protocol was unconventional and overstated cancer risk, leading EPA to calculate an overly stringent assessment of the chemical's cancer risks.

Following a review last spring of a selection of the Ramazzini lab's methanol slides by National Toxicology Program (NTP) pathologists, EPA pulled two finalized Integrated Risk Information System assessments and paused four pending assessments -- including methanol's -- while it considered how to handle the NTP finding that the lab may have been overstating risks.

The source says NTP has indicated that the review of the fuel additive MTBE has already been completed but is waiting on the other three to be finalized so that all four reports can be released together, likely in August. However, the source adds that NTP has said little about what the reports will contain.

**In the draft assessment released in March, EPA proposes a reference dose (RfD),** or safe daily dose for ingestion, of 0.4 mg/kg-day, and a first-time reference concentration (RfC), or safe daily dose for inhalation exposure, of 2 mg/m<sup>3</sup> -- levels industry says are far too conservative. When final, the assessment will update risk estimates that EPA completed in 1988 and will form the basis for a host of regulatory decisions.

More recently, the agency June 22 published an addendum to its draft "Toxicological Review of Methanol (Non-Cancer)," in the *Federal Register*, adding four additional studies -- including three sought by industry -- to the body of research that a panel of peer reviewers will consider prior to making recommendations on how officials should move forward with the risk assessment.

Those studies, which were among a total of five that industry had asked the agency to consider to address concerns with how the agency extrapolated results of animal studies to humans. The studies generally found that methanol metabolizes differently in primates and rabbits than in mice, which EPA relied on when proposing its RfD and RfC.

In particular, industry argued, the three studies that Wells participated in found that rodents are not a good model for effects in humans because rodents are more sensitive to methanol; tests on rabbits are much more accurate because rabbits metabolize the substance in ways similar to humans; and there are differences between methanol's effects on rodents versus its effects on humans (*Risk Policy Report*, June 28).

While EPA included some studies favored by industry, the agency discounted the study results. For example, in its review of the industry backed study by Sweeting et al. (2011), EPA noted that the authors concluded that no statistically significant effects were reported on rabbit growth parameters and mortality but noted that some adverse outcomes, such as postpartum lethality and a shortened gestational period, found in rabbits were also observed in monkeys.

EPA also declined to take into account an additional industry study by Wells that found that human embryos may be less susceptible to methanol due to differences in enzyme activities. EPA, in the addendum, pointed to a different study that suggests that embryo exposure could result in developmental issues.

In comments on the addendum, Greg Dolan, president of the Methanol Institute, says the study that EPA cites "draws overly broad conclusions from a very limited study. That study cannot reasonably support EPA's recommended reference levels for methanol." *The comments are available on*

*InsideEPA.com. (Doc. ID: 2369636)*

Dolan, in his comments, further reiterated concerns raised by industry, that EPA failed to take into account background levels of methanol, which is naturally occurring, when setting its RfC and RfD. "The recommended reference levels in the EPA assessment are further undermined conceptually by the fact that humans produce methanol, independently from any exogenous exposure to methanol itself," he wrote. "Furthermore, the blood levels that naturally result from this endogenous production of methanol are greatly in excess of the blood levels that would result from exposure to methanol at the level of the recommended reference dose for most humans."

Based on EPA's proposed levels, Dolan continued, "a large proportion of the human population is at risk of development effects from methanol it naturally produces and that even a normal glass of orange juice could, by the same logic, result in a toxicologically significant event for the person consuming the juice." -- *Jenny Hopkinson*

Elizabeth Erwin  
Communications Assistant  
National Center for Environmental Assessment  
Office of Research and Development  
U.S. Environmental Protection Agency  
Office: (703) 347-0205  
Fax: (703) 347-8699